

**IN THE CLAIMS:**

**Replace claims 1-32 and 37 as originally filed with amended claims 1-32 and 37.**

1. (Amended) An oral pharmaceutical dosage form comprising at least a  $H^+$ ,  $K^+$ -ATPase inhibitor and a gastric antisecretory prostaglandin analogue compound as active components, and optionally pharmaceutically acceptable excipients, wherein the dosage form is in the form of a fixed unit dosage form.
2. (Amended) The dosage form according to claim 1, wherein the dosage form is a tablet formulation.
3. (Amended) The dosage form according to claim 1, wherein the dosage form is a capsule formulation.
4. (Amended) The dosage form according to claim 1, wherein the  $H^+$ ,  $K^+$ -ATPase inhibitor compound is protected by an enteric coating layer.
5. (Amended) The dosage form according to claim 1, wherein the fixed dosage form further comprises a calcium channel blocking agent.
6. (Amended) The dosage form according to any of claims 1-5, wherein the  $H^+$ ,  $K^+$ -ATPase inhibitor is omeprazole, an alkaline salt thereof, one of its single enantiomer or an alkaline salt thereof.
7. (Amended) The dosage form according to claim 6, wherein the  $H^+$ ,  $K^+$ -ATPase inhibitor is omeprazole magnesium salt.

8. (Amended) The dosage form according to claim 6, wherein the H<sup>+</sup>, K<sup>+</sup>-ATPase inhibitor is S-omeprazole magnesium salt.

9. (Amended) The dosage form according to any of claims 1-5, wherein the H<sup>+</sup>, K<sup>+</sup>-ATPase inhibitor is lansoprazole, one of its single enantiomers or a pharmaceutically acceptable salt thereof.

10. (Amended) The dosage form according to any of claims 1-5, wherein the H<sup>+</sup>, K<sup>+</sup>-ATPase inhibitor is pantoprazole, one of its single enantiomers or a pharmaceutically acceptable salt thereof.

11. (Amended) The dosage form according to claim 1, wherein the gastric antisecretory prostaglandin analogue compound is selected from the group consisting of misoprostol, enisoprost, enprostil, one of the single enantiomers thereof or a pharmaceutical acceptable salt thereof.

12. (Amended) The dosage form according to claim 1, wherein the amount of the H<sup>+</sup>, K<sup>+</sup>-ATPase inhibitor is in the range of 1 - 200 mg and the amount of the gastric antisecretory prostaglandin analogue is in the range of 80 - 1000 µg.

13. (Amended) The dosage form according to claim 1, wherein the amount of the H<sup>+</sup>, K<sup>+</sup>-ATPase inhibitor is in the range of 5 - 80 mg and the amount of the gastric antisecretory prostaglandin analogue is in the range of 100 - 800 µg.

14. (Amended) The tableted dosage form according to claim 2, wherein the tablet consists of two different layers, a first layer comprising the  $H^+$ ,  $K^+$ -ATPase inhibitor and a second layer comprising the gastric antisecretory prostaglandin analogue.

15. (Amended) The tableted dosage form according to claim 2, wherein the tablet formulation is a multiple unit tableted dosage form comprising:

- C  
H
- a) the  $H^+$ ,  $K^+$ -ATPase inhibitor in the form of enteric coating layered pellets,
  - b) the gastric antisecretory prostaglandin analogue compound, and optionally
  - c) pharmaceutically acceptable excipients,
- compressed together into a tablet, wherein the enteric coating layer covering the individual pellets has mechanical properties such that the tableting of the pellets together with the gastric antisecretory prostaglandin analogue and the optional pharmaceutically acceptable excipients does not significantly affect the acid resistance of the enteric coating layered pellets.

16. (Amended) The tableted dosage form according to claim 15, wherein the enteric coating of the individual pellets comprises a plasticized enteric coating layer material.

17. (Amended) The tableted dosage form according to claim 15, wherein the enteric coating layered pellets are further covered with an over-coating layer comprising a film forming polymer and pharmaceutically acceptable excipients.

18. (Amended) The tableted dosage form according to any of claims 15-17, wherein the tablet is divisible.

Sub B2  
19. (Amended) The tableted dosage form according to claim 2, wherein at least one part of the tablet is in the form of an extended release formulation.

20. (Amended) The tablet dosage form according to claim 19, wherein the part of the tablet giving extended release is a hydrophilic matrix.

C1  
21. (Amended) The tablet dosage form according to claim 19, wherein the part of the tablet giving extended release is a hydrophobic matrix.

22. (Amended) The tablet dosage form according to claim 2, wherein the tablet consists of two different layers, a first layer comprising the  $H^+$ ,  $K^+$ -ATPase inhibitor in the form of enteric coating layered pellets compressed with tablet excipients into a layer, and a second layer giving an extended release of the incorporated gastric antisecretory prostaglandin analogue.

23. (Amended) The tableted dosage form according to claim 2, wherein the tablet comprises enteric coating layered pellets of the  $H^+$ ,  $K^+$ -ATPase inhibitor layered with a further layer comprising the gastric antisecretory prostaglandin analogue, and the layered pellets are ? compressed with tablet excipients to form a tablet.

24. (Amended) The tableted dosage form according to claim 23, wherein the pellets before compression to a tablet are covered by a pigmented film coating layer.

25. (Amended) The tablet dosage form according to claim 2, wherein the tablet consists of two types of layered pellets, the first type consisting of enteric coating layered pellets comprising the  $H^+$ ,  $K^+$ -ATPase inhibitor and the second type consisting of pellets

comprising the gastric antisecretory prostaglandin analogue, wherein all pellets are compressed together with tablet excipients to form a tablet.

26. (Amended) The tablet dosage form according to claim 22, wherein the tablet consists of enteric coating layered pellets comprising the  $H^+$ ,  $K^+$ -ATPase inhibitor, and pellets comprising the gastric antisecretory prostaglandin analogue incorporated in a matrix giving an extended release of the prostaglandin analogue.

27. (Amended) The dosage form according to claim 3, wherein the capsule comprises two types of layered pellets, the first type consisting of enteric coating layered pellets comprising the  $H^+$ ,  $K^+$ -ATPase inhibitor, and the second type consisting of pellets comprising the gastric antisecretory prostaglandin analogue, and wherein all pellets and the optional pharmaceutically acceptable excipients are filled in the capsule.

28. (Amended) A process for the manufacture of a fixed dosage form comprising a  $H^+$ ,  $K^+$ -ATPase inhibitor and one or more gastric antisecretory prostaglandin analogue(s) in a capsule, the process comprising the steps of:

- (a) preparing the  $H^+$ ,  $K^+$ -ATPase inhibitor in the form of enteric coating layered pellets,
- (b) preparing the gastric antisecretory prostaglandin analogue in the form of pellets coating layered with an extended release film,
- (c) mixing the  $H^+$ ,  $K^+$ -ATPase inhibitor pellets with the gastric antisecretory prostaglandin analogue pellets, optionally with pharmaceutically acceptable excipients, and
- (d) filling the mixture into capsules.

29. (Amended) A process for the manufacture of a fixed dosage form comprising a  $H^+$ ,  $K^+$ -ATPase inhibitor and one or more gastric antisecretory prostaglandin analogues in a multiple unit tableted dosage form, the process comprising the steps of:

- Sub 83  
Final
- (a) preparing the  $H^+$ ,  $K^+$ -ATPase inhibitor in the form of enteric coating layered pellets,
  - (b) mixing the  $H^+$ ,  $K^+$ -ATPase inhibitor with pellets comprising the gastric antisecretory prostaglandin analogue, and optionally with pharmaceutically acceptable tablets excipients, and
  - (c) compressing the mixture into multiple unit tablets without causing any significant change of the acid resistance of the enteric coating layered pellets.

30. (Amended) A process for the manufacture of a fixed dosage form comprising a  $H^+$ ,  $K^+$ -ATPase inhibitor and one or more gastric antisecretory prostaglandin analogues in a multiple unit tableted dosage form, the process comprising the steps of:

- (a) preparing the  $H^+$ ,  $K^+$ -ATPase inhibitor in the form of enteric coating layered pellets,
- (b) preparing the gastric antisecretory prostaglandin analogue in the form of coating layered pellets wherein the coating layer is an extended release layer,
- (c) mixing the  $H^+$ ,  $K^+$ -ATPase inhibitor pellets with the antisecretory prostaglandin analogue pellets and optionally with pharmaceutically acceptable tablet excipients, and
- (d) compressing the mixture into tablets without causing any significant change of the acid resistance of the enteric coating layered pellets.

31. (Amended) A method for the treatment and prophylaxis of gastrointestinal disorders by administering to a host in need thereof a therapeutically effective dosage form according to any of claims 1-5.

A1  
32. (Amended) A method for avoiding gastrointestinal side-effects normally associated with gastric antisecretory prostaglandin analogue medicament treatment by administering to a host in need thereof a therapeutically effective dosage form according to any of claims 1-5.

**Cancel claims 33 and 34.**

35. (Not amended herein) A combination of a  $H^+$ ,  $K^+$ -ATPase inhibitor, a gastric antisecretory prostaglandin analogue and a calcium channel blocking agent in the treatment of gastrointestinal diseases.

36. (Not amended herein) A blister pack comprising a  $H^+$ ,  $K^+$ -ATPase inhibitor medicament and a gastric antisecretory prostaglandin analogue medicament.

Sub A2  
37. (Amended) The blister pack according to claim 36 comprising an additional medicament which is a calcium channel blocking agent.

**Add new claims 38 and 39.**

Sub A3  
38. (New) The dosage form according to claim 4, wherein a separating layer is applied under the enteric coating separating the  $H^+$ ,  $K^+$ -ATPase inhibitor from the enteric coating layer.

39. (New) The tableted dosage form according to claim 23, wherein the compressed tablet is covered by a pigmented tablet coat.